



Consumer Federation of America

1620 I Street, N.W., Suite 200 * Washington, DC 20006

September 28, 2006

Representative Henry A. Waxman
United States House of Representatives
Washington, D.C. 20515

Dear Representative Waxman:

The Consumer Federation of America strongly supports your legislation to create a clear regulatory “road map” that would permit the approval of safe, cost-effective generic biologic medicines. The essential first step in spurring the development of a vibrant market for biogenerics is creating a well-defined regulatory process based on rigorous scientific standards of interchangeability and comparability. It has become clear that the FDA will not act on its own to create such an abbreviated pathway for all biologic medicines, so it is essential that Congress provide legislative direction.

Biologic medicines such as human insulin, and interferons already offer crucial treatments that improve the health and quality-of-life of millions of Americans. With many potential biologic advances in the pipeline, biologics offer extraordinary promise in the treatment of many diseases and illness – but at extraordinary cost. Biologics are already a major driver of increasing prescription drug prices. Sales of biotechnology products could exceed \$60 billion by 2010, according to some estimates. These medicines often cost thousands of dollars a month and as much as \$150,000 a year. Such costs put important biologic therapies out of reach for many Americans, especially those with no or poor-quality health insurance.

Congress should not wait until the extremely high costs of biologic therapies are crippling the health care system before it clears a path for biogenerics in the United States. Comprehensive guidelines for the approval and regulation of safe and efficacious biogenerics have already been created by the European Medicines’ Agency. Americans deserve the same opportunity to cut costs on important but very expensive biologic medicines.

Sincerely,

Travis B. Plunkett
Legislative Director